REMARKS

This application was filed with 27 claims. Claims 1-4, 6-9 and 15-27 have been rejected. Claims 1, 2, 9, 15, 17, 18, 21, 22, 25, 26, and 27 have been amended. Therefore, Claims 1-27 are pending in the Application. Reconsideration of the application based on the remaining claims as amended and arguments submitted below is respectfully requested.

Amendments to the Specification

A new Abstract has been supplied to more closely conform the length of the Abstract to the comments on page 2 of the Office Action.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 1-4, 6, 9, 15, 17, 18, and 20-27 have been rejected under 35 U.S.C. §102(b) as being anticipated by Braithwaite (U.S. Patent No. 6,347,629).

Applicant respectfully submits that Braithwaite does not anticipate the rejected claims because the Braithwaite inhaler and the present invention are entirely different devices that operate on different principles to achieve different ends. Braithwaite discloses a dry powder inhaler that captures larger particles of powder in a mouthpiece device that induces cyclonic flow. Larger powder particles are caused by the design of the device to impact on the walls of the device, thereby preventing their trapping the particles to prevent inhalation. Applicant's claimed invention is not an inhaler. Rather, the present invention is a spacer that connects

to an inhaler and, after receiving a medication spray dispensed by the inhaler, prevents the impaction of drug particles on the walls of the spacer. If a metered dose inhaler is used, the spacer reduces the size of liquid droplets through evaporation during transit through the spacer.

Further, Applicant's spacer and the Braithwaite inhaler are comprised of different components. For example, the spacer of the present invention comprises two bodies (chambers), air inlets downstream of the point of attachment to the inhaler, and a mouthpiece that is strictly for positioning in the mouth of the patient These bodies are external to an inhaler. An inhaler also has an integrated mouthpiece as described in the Braithwaite patent. In contrast, Braithwaite discloses a single chamber attached to the integral mouthpiece of an inhaler. The air inlet in Braithwaite is only internal to the inhaler, distal to the spray inlet. The Braithwaite device, contrary to accepted terminology of "spacer" or "holding chamber", is generally termed a "mouthpiece". Thus, the rejection of Applicant's claims based on Braithwaite is based on the inclusion of the inhaler device (integral mouthpiece). However, the present invention is a spacer that is attached to an inhaler and therefore does not comprise an inhaler or any part thereof.

With respect to Claim 1, the Office Action states that Braithwaite (Figure 9) teaches a spacer for delivering medication spray into the lungs of a patient comprising a first body (formed by components 94 and 98) having a large diameter distal end and a small diameter proximal end, a second body (formed by component 92) having a large diameter distal end and a small diameter proximal end joined to

joined to the distal end of the first body, a mouthpiece 99 positioned at the proximal end of the first body, a spray inlet 45 positioned at the distal end of the second body, and the first body further comprising a first internal chamber and second body comprising a second internal chamber, the first and second internal chambers forming a spray conduit having a continuous spray passage from the spray inlet to the mouthpiece. As noted above, Braithwaite discloses a powder inhaler, not a spacer. Claims 1, 9, and 15 have been amended to clarify that the present invention is not an inhaler but a device (spacer) that receives a medication spray from an inhaler external to the device.

Figure 9 of Braithwaite and the accompanying description (column 8, line 25 – column 9, line 27) disclose a mouthpiece device 93 comprising discs 94 and 95, a cover disc 97, and, a hollow cap 98 having an open-ended tubular extension 99. The disc 94 has a slot 94a that is fitted to the outer wall of an inhaler mouthpiece. The rejection of Claim 1 appears to be based on an interpretation of Braithwaite's Figure 9 in which the hollow cap 98 and disc 94 of the mouthpiece are equated with the presently claimed first body, the mouthpiece 92 of the inhaler is equated with the presently claimed second body, the open-ended tubular extension 99 of the of the hollow cap 98 is equated with the presently claimed mouthpiece, and a spray inlet 45 (not found in Figure 9 but shown in Figures 3, 4, and 6) is equated with the claimed spray inlet. Braithwaite does not anticipate Claim 1 because the "second body" referenced by the Office Action as disclosed in Braithwaite cannot be the second body of the present invention as claimed. Those skilled in the art of inhaler

drug delivery understand that a spacer is used to transport medication from the outlet of a metered dose inhaler to a patient's mouth. This is described in paragraphs 7 and 35 and illustrated in Figures 5 and 7 of Applicant's disclosure. In other words, the spacer is not an integral part of the inhaler and the inhaler is not an integral part of the spacer.

The mouthpiece device disclosed by Braithwaite has two parts: an inhaler 91 and an inhaler mouthpiece 92. The presently claimed invention is a spacer, which does not include an inhaler. The mouthpiece 92 of the inhaler 91 in Braithwaite cannot be interpreted as equivalent to the second body of the presently claimed invention because it is disclosed as being a part of the inhaler. Column 8, lines 30-34 of Braithwaite state as follows: "The mouthpiece device 93 comprises a disc 94, having a slot 94a, within which is fitted the outer wall of the inhaler mouthpiece 92, a cylindrical disc 95 having arcuate slots 96 in it, a cover disc 97, and a hollow cap 98 having an open-ended tubular extension 99." (emphasis added) As shown in Applicant's Figures 5 and 7, an inhaler is connected to the claimed spacer through the mouthpiece of the inhaler. Consequently, the mouthpiece device disclosed by Braithwaite does not comprise two bodies as recited in Claim 1.

Claim 1 also requires a spray inlet. A spray inlet is a point of attachment for receiving medication from a dispensing inhaler, as described in Applicant's specification at paragraph 35, lines 11-13. Looking at the spray inlet 45 shown in Figures 3 and 4 of Braithwaite, it is noted that only one body portion 49 is disclosed proximal to the spray inlet 45. Figure 1 in Braithwaite discloses an "inlet 5 into

which the integral mouthpiece 2 of the inhaler 1 is engaged." (col. 4, lines 65-66) This inlet is distal to a single body in Figures 1 and 9 (the mouthpiece of the inhaler is labeled 92 in Figure 9), and not two bodies. By comparison, a proper reading of Claim 1 requires that each of the first and second bodies is proximal to the spray inlet. Thus, Braithwaite does not anticipate Claim 1 because it does not disclose a spray inlet distal to a second body.

Claim 2 is dependent on Claim 1 and should be allowable. Also with respect to Claim 2, the Office Action asserts that Braithwaite "teaches a spacer further comprising a plurality of air inlets 90 passing through the first body, the air inlets positioned downstream from the spray inlet near the distal end of the first conical body." Column 8, lines 65-67 of Braithwaite describes these air inlets 90 as follows: "In this manner there are formed spiral passageways 90 leading from the inhaler mouthpiece 92 to a cyclone chamber 100..." Thus, the passageways 90 connect the flow of drug from the inhaler mouthpiece to the cyclone chamber. The air inlets in Claim 2 as amended cannot be interpreted as passageways between an inhaler mouthpiece and a chamber, or body, in the spacer because the claim recites that the air inlets allow external air to pass into the first chamber. Accordingly, Braithwaite does not anticipate Claim 2 because it does not disclose air inlets positioned downstream from the spray inlet and that allow external air to pass into the first chamber.

Claims 3 and 4 are dependent on Claim 2 and therefore should be allowable.

Claim 6 is dependent on Claim 1 and therefore should be allowable.

With respect to Claim 9, the arguments presented above with respect to Claim 1 (distinguishing the bodies or chambers of an inhaler or inhaler mouthpiece from those used in a spacer) are applicable, as are the arguments regarding the spray inlet made with respect to Claim 1. Also, the Office Action states that Braithwaite teaches a spacer comprising "a conduit (formed by 92, 94, 98) having a proximal end and a distal end; a spray inlet at 45 attached to the distal end of the conduit, the spray inlet adapted for receiving medication spray from the inhaler; a mouthpiece 99 attached to the distal [proximal] end of the conduit, the conduit including at least one interior chamber defining a continuous spray passage from the spray inlet to the mouthpiece; and at least one air inlet 90 passing through the wall of the conduit, the air inlet positioned downstream from the spray inlet." The Office Action correctly states that component 45 in Braithwaite is a spray inlet, but goes on to state that spray inlet 45 is attached to the distal end of a conduit formed by 92, 94, 98. Spray inlet 45 is not shown in any drawing figure together with components 92, 94, or 98. However, Figure 3 of Braithwaite clearly shows that spray inlet 45 would be between 92 and 94 in Figure 9 and is therefore not distal to a conduit that includes 92 and 94. Consequently, Braithwaite does not disclose a conduit having a proximal end and a distal end and a spray inlet attached to the distal end of the conduit.

Also, the Office Action asserts that element 90 in Figure 9 of Braithwaite is an air inlet, which is not the case as explained in the arguments above with respect to Claim 2.

In summary, Braithwaite does not anticipate Claim 9 as amended because Braithwaite does not disclose a conduit having a proximal end and a distal end, and a spray inlet attached to the distal end of the conduit, or at least one air inlet passing through the wall of the conduit, the air inlet positioned downstream from the spray inlet.

With respect to Claim 15 as amended, the arguments presented above with respect to Claim 1 (distinguishing the chambers of an inhaler or inhaler mouthpiece from a spacer) are applicable as are the arguments presented with respect to the spray inlet and Claim 1.

Claims 17, 18, and 20 are dependent on Claim 15 and therefore should be allowable. With further respect to Claims 17, 18, and 20, as explained in the arguments above in response to the rejection of Claim 2, component 90 in Figure 9 of Braithwaite is disclosed as being a passageway "leading from the inhaler mouthpiece 92 to a cyclone chamber". The passageway 90 is not an air inlet that allows external air to pass into the first chamber, as clarified in Claim 17 as amended.

Claim 21 as amended also recites that the air inlets allow external air to pass into the chamber, a feature not taught in Braithwaite. Claim 22 is dependent on Claim 21 and should also be allowable.

With respect to Claim 23, Braithwaite discloses a device that receives powder from an inhaler and generates centrifugal forces (i.e. toward the outer walls of the chamber) to separate lighter particles from heavier ones. The heavier particles are

directed into the walls of the chamber, not away from them as recited in Claim 23 (see col. 3, line 44 – col. 4, line 1). As seen in Figures 1 and 2 of Braithwaite, and looking more particularly at arrows 44, C and D, the medication particles are clearly being intentionally directed by contact with the walls of the device. Consequently, Braithwaite does not anticipate Claim 23 because it fails to disclose recirculation zones functional to inhibit contact between the medication spray and the spacer walls.

Claims 24 and 25 are dependent on Claim 23 and therefore should be allowable. Also, Claim 25 as amended includes the limitation that the air inlets allow external air into the chamber, a feature not taught in Braithwaite.

With respect to Claim 26, the Office Action states that Braithwaite teaches "...spacer geometry to generate high-pressure recirculation zones at 100, 101 inside the spacer; and using the high-pressure recirculation zones and external airflow to direct the medication spray away form the walls of the spacer and out of the mouthpiece end of the spacer." Applicant respectfully submits that Braithwaite does not disclose any external airflow, only flow from the inhaler. Also, Braithwaite discusses only negative pressure, not positive pressure forces. Furthermore, the centrifugal airflow is altered in the Braithwaite device specifically to prevent the inhalation of large particles by directing them into the walls of the air circulation chamber (See Figures 2, 7, and 8 of Braithwaite). The summary of the invention in column 2 clearly states that the purpose of the Braithwaite device is to prevent heavier particles from reaching the outlet of the device. These heavier particles are

captured within the walls of chamber 35 shown in Figure 2, as described in col. 6, lines 26-51. Accordingly, Braithwaite does not anticipate Claim 26 because if there are any recirculation zones in the Braithwaite device, they do not function to inhibit contact between medication particles and the walls of the device.

Claim 27 is dependent on Claim 26 and therefore should be allowable. Also, Claim 27 as amended includes the limitation that the air inlets allow external air into the spacer, a feature not taught in Braithwaite.

For all of the foregoing reasons, Applicant submits that the rejection of Claims 1-4, 6, 9, 15, 17, 18, and 20-27 under 35 U.S.C. §102(b) should be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

Claims 7, 8, 16, and 19 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Braithwaite. Applicant submits that Braithwaite cannot render any of Applicant's claims obvious because the Braithwaite device is an inhaler or inhaler mouthpiece, not a spacer. The purposes and functions of the devices are distinct and different.

In particular, the Office Action asserts as to Claims 7, 8 and 19 that Braithwaite "teaches essentially all of the limitations except for wherein the first and second bodies have an elliptical shape or oblong shape and wherein the air inlet is oblong." As a further response to this rejection, Applicant notes that Claims 7 and 8 are dependent on Claim 1 and Claim 19 is dependent on Claims 15 and 17. Therefore, the arguments presented above with respect to Claims 1 and 15 (distinguishing the bodies or chambers of an inhaler or inhaler mouthpiece from

those used in a spacer) are applicable, as are the arguments presented above regarding the spray inlet with respect to Claims 1, 15, and 17. Braithwaite fails to teach a spray inlet distal to a second body. Also, Braithwaite teaches only a spray inlet – not an air inlet - and no air enters the Braithwaite device proximal to the spray inlet.

The Office Action also asserts that "it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the shape of the bodies and air inlet of Braithwaite of any particular geometric shape" and argues that "the Applicant has not disclosed that the specific geometry provides an advantage, is used for a specific purpose, or solves a stated problem." The Office Action also states that any shape would work equally well and would perform the same function "of reducing the particle size of the medicament and providing a passageway for air." Applicant believes that this argument can be summarized as follows: Because Applicant did not disclose specific advantages for the claimed geometry, the claimed geometry would have been obvious to one of ordinary skill in the art. Applicant does not agree with this "design choice" reasoning. The Office Action does not cite any reference teaching any such geometries from which a designer could make such a "design choice." Moreover, the "design choice" argument presumes that the designer understands that he or she is choosing a geometry for purposes of creating a recirculation zone that keeps the medication particles away from the walls of the spacer. The Office Action does not identify any such teaching. Nevertheless, Applicant refers the Examiner to paragraphs 14, 40-

43, 48, and 49 in the present application in which the importance of geometry and external airflow combined with geometry are discussed.

The summaries of the inventions in the Braithwaite patent and in the present application clearly define different and incompatible airflows and advantages. The stated purpose of the Braithwaite device is to segregate particles based on size and to prevent inhalation of large particles ejected from a dry powder inhaler (summary of the invention). Applicant's invention facilitates inhalation of all particles from an inhaler and, if the medicine is dispensed by the inhaler as solution droplets, allows evaporation of the droplets before they are inhaled. Applicant's invention does not segregate particles based on size. Accordingly, it would not be obvious to one of ordinary skill in the art at the time that the invention was made to modify the Braithwaite dry powder inhaler mouthpiece to have a passageway designed to prevent particles from impacting the walls of the passageway.

Claim 16 is dependent on Claim 15 and should be allowable for the reasons discussed above as to Claim 15. Further, paragraph 16 of the Office Action presents an argument that is not understood by Applicant. Applicant agrees that a collapsible spacer represents only one embodiment of the invention. Whether or not a person of ordinary skill in the art would expect the inhaler of Braithwaite to work as well as a collapsible device is not a relevant question unless there is some teaching in the art for making a collapsible spacer or even a collapsible inhaler.

The Office Action cites no such teaching. Therefore, it appears that impermissible hindsight is being used to reject Claim 16.

Applicant respectfully submits that the rejections of Claims 7, 8, 16, and 19 under 35 U.S.C. § 103(a) should be withdrawn.

Allowable Subject Matter

Claims 5 and 10-14 have been objected to as being dependent on a rejected base claim but have been deemed allowable if re-written in independent form to include all of the limitations of the base claim and of any intervening claims. At the present time, Applicant has not amended these claims to independent form because Applicant believes that the base claims are allowable for the reasons stated above.

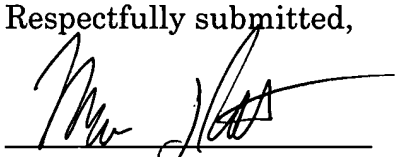
Applicant has commented on some of the distinctions between the cited references and the claims to facilitate a better understanding of the present invention. This discussion is not exhaustive of the facets of the invention, and Applicant hereby reserves the right to present additional distinctions as appropriate. Furthermore, while these remarks may employ shortened, more specific, or variant descriptions of some of the claim language, Applicant respectfully notes that these remarks are not to be used to create implied limitations in the claims and only the actual wording of the claims should be considered against these references.

Pursuant to 37 C.F.R. § 1.136(a), Applicant petitions the Commissioner to extend the time for responding to the February 8, 2005, Office Action for one month from May 8, 2005, to June 8, 2005. Applicant encloses herewith a check in the

amount of $60 made payable to the Director of the USPTO for the petition fee.

The Commissioner is authorized to charge any deficiency or credit any overpayment associated with the filing of this Response to Deposit Account 23-0035.

Respectfully submitted,



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CERTIFICATE OF MAILING

I hereby certify that this Response and Amendment, along with a check in the amount of $60 for the extension fee are being transmitted via First Class Mail, postage pre-paid, to:

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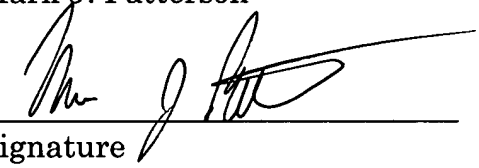
Mark J. Patterson



Signature
Registration Number 30,412

May 25, 2005

Date